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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/509,024

09/27/2004

Sophi Anne Michele Bozonnet

2121-0183PUSI

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| EXAMINER |
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FRONDA, CHRISTIAN L

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| ART UNIT | PAPER NUMBER |
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1652

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

09/24/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/509,024   | <b>Applicant(s)</b><br>BOZONNET ET AL. |  |
|                              | <b>Examiner</b><br>Christian L. Fronda | <b>Art Unit</b><br>1652                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 19-26 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-35 is/are allowed.
- 6) ☒ Claim(s) 9-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. The previous Office Action dated 07/25/2007 has been withdrawn in view of errors in the action and error in applicants' claim set filed 06/27/2007.
2. In the amendment dated 06/27/2007, the attached claim set is missing claim number 27. Rejections and/or objections stated in the instant Office Action are based on the defective claim set filed 06/27/2007, which is missing claim number 27.  
Appropriate correction is requested.
3. Claims 1-26 and 28-35 are pending in the application, based on the defective claim set filed 06/27/2007. Claims 1-8 and 19-26 have been previously withdrawn from consideration.
4. Claims 9-18 and new claims 28-35 are under consideration in this Office Action.
5. The declaration of Deposit of Microorganism attached to the amendment dated 06/27/2007 has been acknowledged. The declaration of Deposit of Microorganism overcomes the grounds of rejection of claims 13 and 18 under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement.
6. The previous grounds of rejection of claims 9-12, 17, 18 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' amendment to the claims in the amendment dated 06/27/2007.
7. The information disclosure statement filed 09/27/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 11, 13, 14, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as

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being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the phrase “a complementary strand to SEQ ID NO: 4” which renders the claim vague and indefinite since it is not clear if the claim encompasses the full complement of SEQ ID NO: 4 or fragments. Dependent claims 14 and 31 are also rejected because the claim does not correct this defect. It is suggested that the claim recite “the full complement of SQ ID NO: 4”.

Claim 13 recites the phrase “a complementary sequence to the sequence in a)” which renders the claim vague and indefinite since it is not clear if the claim encompasses the full complement or fragments. Dependent claim 33 is also rejected because the claim does not correct this defect. It is suggested that the claim recite the phrase “the full complement”.

***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 9-18 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nuclei acid consisting of SEQ ID NO: 4 encoding a dextranucrase that can form that can form dextrans having  $\alpha(1 \rightarrow 2)$  linkages from saccharose,  $\alpha$ -D-fluoroglucose, para-nitrophenyl- $\alpha$ -D-glucopyranoside,  $\alpha$ -D-glucopyranoside- $\alpha$ -D-sorbofuranoside or 4-O- $\alpha$ -D-galactopyranosylsucrose; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments filed 06/27/2007 have been fully considered but are not persuasive for the reasons of record as supplemented below. As stated previously, the specification provides guidance and working example for of SEQ ID NO: 4 encoding a dextranucrase that can form that can form dextrans having  $\alpha(1 \rightarrow 2)$  linkages from saccharose,  $\alpha$ -D-fluoroglucose, para-nitrophenyl- $\alpha$ -D-glucopyranoside,  $\alpha$ -D-glucopyranoside- $\alpha$ -D-sorbofuranoside or 4-O- $\alpha$ -D-galactopyranosylsucrose. However, the specification does not provide guidance, working examples, or prediction for making and/or using any isolated nucleic acid encoding an enzyme with glycosyltransferase activity comprising at least one nucleotide sequence encoding a catalytic domain having at least 80% identity with SEQ ID NO: 3, any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to SEQ ID NO: 4, and any isolated nucleic acid encoding an enzyme with glycosyltransferase activity having at least 80% identity to the sequence encoding a dextranucrase expressed by a plasmid deposited with

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accession number I-2649.

SEQ ID NO: 3 is disclosed as consisting of 2568 nucleotides and SEQ ID NO: 4 is disclosed as consisting of 8506 nucleotides. The recitation of 80% identity requires at least 513 nucleotides that must be altered in SEQ ID NO: 3 and 1701 nucleotides in SEQ ID NO: 4. Trial and error experimentation must be performed to include searching and screening for 513 specific nucleotide changes (nucleotide deletion, insertion, addition, substitutions, and combinations thereof) in SEQ ID NO: 3 and 1701 specific nucleotide changes (nucleotide deletion, insertion, addition, substitutions, and combinations thereof) in SEQ ID NO: 4 that will result in a nucleic acid that will still encode a functional enzyme. Furthermore, since the specific nucleotide sequence of the sequence encoding a dextranucrase expressed by a plasmid deposited with accession number I-2649, one skilled in the art would not know the number of specific nucleotides must be altered to meet the claim limitation of 80% identity to the sequence encoding a dextranucrase expressed by a plasmid deposited with accession number I-2649. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention. Thus, the experimentation left to those skilled in the art to make and/or use the invention is unnecessarily, and improperly, extensive and undue.

It is noted that arguments were not presented to traverse the grounds of rejection on claim 11. Thus, the claim stands rejected for reasons of record as restated here. Claim 11 is directed to a polynucleotide sequence that hybridizes to the disclosed sequences, Applicants have not sufficiently defined the conditions under which the hybridizations are to take place. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory.

Therefore, without a clear and explicit recitation of the conditions, which were actually used by Applicants in isolating the claimed polynucleotides that hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in claim 11 the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

### *Conclusion*

13. Claims 28-35 are allowed.

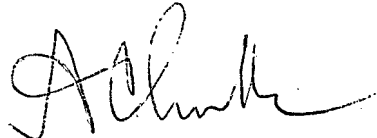
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14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). CLF

  
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